Cancer Clinical Trials Advisory Council
Meeting Minutes
February 28, 2012
Wingate Inn, Bozeman, MT, and by phone

Council members present
Kristin Page Nei, American Cancer Society Cancer Action Network
Dr. Schallenkamp for Dr. Robert Geller, Billings Clinic
Ron Dewsnup, Allegiance Benefit Plan Management
Sharon DeJongh, Bozeman Deaconess Cancer Center
Paul Burns, Cancer Patient
Jo Duszkiewicz, Billings Clinic
Dr. Jack Hensold, Bozeman Deaconess Cancer Center
Dr. Ben Marchello, Frontier Cancer Center and Montana Cancer Consortium
Rachel Peura for Monica Berner, BCBS of MT
Dr. Grant Harrer, Benefis Health System
Diane Ruff, Associated Employers Group Benefit Plan & Trust

Council members absent
Monica Berner, BCBS of MT
Paul Bogumill, Mountain West Benefits
Dr. Robert Geller, Billings Clinic
Cory Hartman, New West Health Services
Russ Hill, DOA-Health Care and Benefits Administration
Michael Foster, Catholic Hospitals
Cori Cook, EBMS
Brendan Steele, Cancer Patient
Marien Diaz, Symetra Life Insurance Company

CSI Staff Present
Christine Kaufmann
Amanda Roccabruna Eby – Minutes recorder

Public Attendance
Kathleen Williams, Representative HD 65
Amber Ireland, Montana Municipal Interlocal Authority
Amanda Dinsdale, Montana Cancer Consortium
Becky Franks
Janet May

1. Welcome by Chair, review of agenda, and discussion of deadlines and remaining tasks

Dr. Hensold moved and Jo Duszkiewicz seconded a motion to adopt the minutes with the corrected spelling of two names. The motion was approved unanimously.

2. Barriers to Access Discussion

A working draft document was presented by the "barriers" subcommittee that examined the following topics as potential barriers:

Potential Barrier #1—Plan exclusions for "experimental and investigational"

Council members agreed this was the primary barrier. Most plan documents logically consider the trial itself to be experimental, and many cannot separate the trial from the routine care. The barrier was due to lack of a common definition of routine care which was causing denials for all phases of trials. The

council discussed whether to require coverage in legislation, or ask for voluntary compliance with an agreement, and wondered if both may be needed. **Ron Dewsnup moved, and Ben Marchello seconded a motion that "The advisory council recommends that plan documents and benefit policies cover routine care for anyone enrolled in a clinical trial, based on the routine care definition as defined by the advisory council." The motion passed unanimously.**

Potential Barrier #2—Added cost for out-of-state treatment

Council members discussed plan language in regard to trials being in or out-of-state, and suggested that the issue did not apply to coverage. **Rachel Peura moved, and Jack seconded a motion not to include #2 as a remaining barrier. The motion passed unanimously.**

Potential Barrier #3—Confusion over plan language

Council members agreed the proposed recommendation #1 should clear up confusion about what a plan will cover. **Jo Duszkiewicz moved, and Paul Burns seconded a motion not to include #3 as a remaining barrier. The motion passed unanimously.**

Potential Barrier #4—Contract considerations

Council members agreed the proposed recommendation #1 covered issues related to contract language. **Jack Hensold moved, and Jo Duszkiewicz seconded a motion not to include #4 as a remaining barrier. The motion passed unanimously.**

Potential Barrier #5—Lack of clarity over trial protocols and who covers complications

Council members decided not to make an additional recommendation around the issue of complications that occur during the time period of a trial. The language in the definition does not exclude complications from coverage and therefore will be treated as it would be for any other patient. Council members agreed the type and format of information that payers need for coverage decisions could be more standardized, so procedures are more predictable and clinics know what information to send. The summaries of protocols for trials on the NCI website could be a good start to standardization. Non-NCI trials may also have summary protocols available. A standard format will help hospitals administrators create a summary page for the trials that don't have protocol summaries available. **Jo Duszkiewicz moved, and Paul Burns seconded a motion to form a subcommittee to recommend a standard request form to be proposed by payers and responded to by providers. Rachel Peura voted "nay," all others voted in favor of the motion. Cori Cook, Ron Dewsnup, Jo Duszkiewicz, and Sharon DeJongh will be on the subcommittee.**

Barrier #6—Fear of "off-label" trials

Council members agreed the proposed recommendation #1 clarifies that "off-label" uses of drugs are not clinical trials. **Dr. Schallenkamp moved, and Rachel Peura seconded a motion not to include #6 as a remaining barrier.**

Barrier#7—Lack of data

Council members agreed that collection of additional data would be unlikely to achieve desired results in a cost effective manner. **Jo Duszkiewicz moved, and Dr. Schallenkamp seconded a motion to table the issue. The motion passed unanimously.**

Barrier#8—Differences between fully-insured and self-insured plans

Council members considered proposing a voluntary agreement/compliance from the self-funded companies before 2014. Amber Ireland from MMI said that group plans like hers would feel much more comfortable with a voluntary agreement than any talk of a mandate. Many self-funded plans have adopted state mandates in the past even though they aren't required to, for ease of claims processing**. Jo Duszkiewicz moved, and Jack Hensold seconded a motion or the council to propose a voluntary agreement for self-funded plans to enter into with the insurance commissioner stating that they will comply with the council's adopted definition of routine care. The motion passed unanimously.**

Proposed Barriers #9—Added costs of treatment in trials; #10— Lack of information about trials by insurers; #11— Lack of information about trials by self-funded employer plans; #14—lack of information about differences between trials in four phases

Council members agreed these were important educational tasks but any policy considerations that were covered by the recommendation in #1. **Paul Burns moved, and Sharon DeJongh seconded a motion not to include all of these topics as remaining barriers. The motion passed unanimously.**

Barrier #12—Concerns about stop loss coverage

Council members discussed the issue of stop loss coverage, and thought it was a consideration for self-funded plans, but not a barrier. They agreed that it should be included as a consideration in the voluntary agreement that will be created for self-funded plans, but that stop loss insurers would respond to the employers Summary Plan Document, and research showing cost is not an issue.

Barrier #13—Inconsistent coverage decisions

Council members agreed this potential barrier has already been addressed in #5 and no further comment was needed.

Barrier #15—Patient fears

Council members agreed that education needs to be done on these issues.

3. Findings and Recommendations for final report

The council still needs to discuss inclusion of Medicaid and the state employee health plan in legislation or agreements. A council member proposed Education, Policy, and Process to be the categories for the section on the study activities of the advisory council. Members agreed that many of the potential barriers were able to be dismissed because the council members had educated one another. They agreed the report should recommend establishing a systemic plan for education so that it continues into the future.

The report should document what the council learned so the findings should include the barriers that were stricken. All of the issues that were worked through can be very positive arguments for legislation, especially everything that was learned about costs.

4. Public Comment

Becky Franks-

She appreciates all the work the council is doing. She has talked to many people who just quit once they got a "no" from the insurance company and didn't appeal so much of that data the council discussed, just doesn't exist. She noted the following: When a patient's clinical trial coverage was denied, they just tried something different right away instead of calling the insurance commissioner or appealing. Therefore, it may not be possible to collect accurate data on that topic. It is important for her to work with the patient's physician to find the best possible care for them and this issue completely derails that – they cannot pick the best line of treatment because they cannot get it covered, that conversation should be between the patient and the physician. It becomes a complicated issue when it becomes a conversation with the insurance company. It actually becomes a very simple issue when a person is simply fighting for their life.

Kathleen Williams-

Kathleen commented that the council needs to figure out if the voluntary agreement is plan B, because the legislature may see that as disincentive to pass legislation. She further noted the following: Mike Foster suggested the interim committee proposing a committee bill. The council has to be clear on what the primary recommendations are so the legislature doesn't get confused and derail from passing anything. The way this study bill passed was by talking about "eliminating denials" rather than "mandating coverage." Instead, talk about defining care, solving an issue, prohibiting care, etc.

Janet May-

She is a 3 year breast cancer survivor and the drug that saved her life was a clinical trial. She knows how stressful it is to hear that you cannot start treatment until your insurance coverage begins. She was very lucky but wants to be there for those that weren't so lucky. There is no voice for patients or map for them to strategize through their insurance plans.

The meeting adjourned at 4:11pm